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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,990	12/22/2000	Su-Syin S. Wu	JOHNA.37C1CP1	8376
27777	7590	07/12/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,990

Applicant(s)

WU ET AL

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,6-10,13,15-17 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1,4,6-10,15-17,20-25,27 and 28 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 112***

1. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 limits the medical device of claim 1 to a connector housing or a luer lock. However, claim 1 requires a medical device having a first and second part which are rotatable with respect to one another about a pivot. Neither a connector housing nor a luer lock have this type of configuration. Although Applicant argues that two parts rotating into locking engagement about each other forms a pivot, the Examiner respectfully disagrees. A pivot is a fixed point about which something rotates. Neither a luer lock nor a connector housing feature two parts which rotate about a fixed point.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

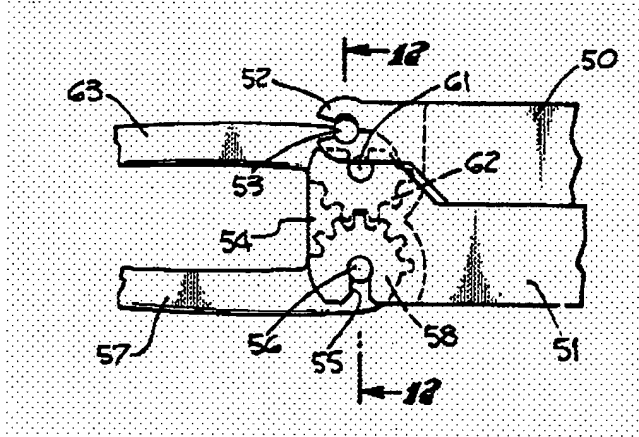
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 6, 15, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Markham (U.S. Patent No. 5,176,699).

Markham teaches a medical device (forceps) comprising a first part 57 and second part 63 rotatable with respect to one another about a pivot 54 and having a contact area

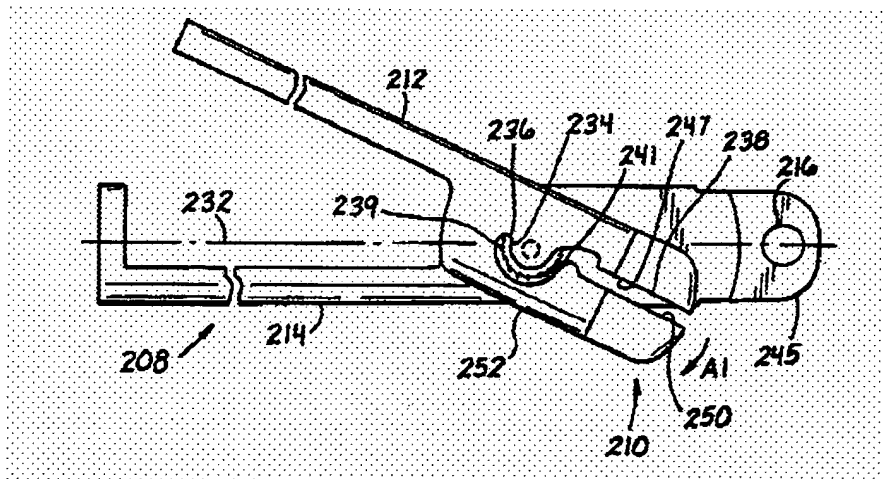
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58,62 therebetween. The contact area comprises a plurality of regular, straight, parallel, grooved projections/lines (e.g. gears) on both the first and second part.



4. Claims 1, 4, 6, 15, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sackier et al (U.S. Patent No. 5,776,146).

Sackier et al discloses a medical device (surgical clamp/holder) having a first part 214 and a second part 212 rotatable with respect to one another about a pivot and having a contact area therebetween at the pivot, wherein the contact area comprises a plurality of regular, straight, parallel, grooved projections/lines at 239.



***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markham or Sackier et al.

Although not specifically disclosed by Markham and Sackier et al, it is deemed obvious to fabricate the medical devices from non-reactive metals (e.g. surgical grade stainless steel) and polymers, as is well-known in the art.

7. Claims 16, 17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schad (WO 96/30058) in view of either Markham or Sackier et al.

Schad teaches a method of cleaning and disinfecting surgical forceps within a chamber, wherein the forceps are contacted with a cleaning/disinfecting fluid within a vessel 4 while being moved. The method achieves a surgical instrument suitable for reuse. Although Schad does not disclose that the forceps have a plurality of projections on a contact area at the pivot point, both of Markham and Sackier et al evidence that this is the common configuration found in medical forceps. Therefore, it would have been obvious to employ the method of Schad to clean and disinfect the surgical forceps of the prior art, as it has been shown to be effective in cleaning forceps.

With respect to circulating the fluid in the vessel 4, Schad discloses that the fluid is hot steam of about 120 °C (col.4, lines 1-5). It would have been obvious to circulate the steam within the vessel during the step of contacting, in order to equalize the

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sterilization temperature within the vessel thereby assuring that the forceps achieves the sterilization temperature.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (U.S. 5,447,684) in view of Markham or Sackier et al..

Williams teaches a method of sterilizing a medical device **H** wherein the medical device is placed within a container **10**, contacted with a sterilizing fluid, and the pressure reduced. See Figure 6 and col.8, lines 6-32. Williams discloses, in general, the sterilization of medical instruments and does not specifically teach sterilization of a medical device having a first part and second part rotatable with respect to one another about a pivot.

Both of Markham and Sackier et al. teach a surgical instrument having a first part and second part rotatable with respect to one another about a pivot and having a plurality of projections on a contact area at the pivot point. As reusable surgical instruments like those disclosed by Markham and Sackier et al. must necessarily be sterilized before reuse and as the method of Williams is effective in the sterilization of medical instruments, it would have been obvious to employ the method of Williams to sterilize the instruments of either Markham or Sackier et al..

***Allowable Subject Matter***

9. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 13 is allowed.

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11. The following is a statement of reasons for the indication of allowable subject matter: In the medical device of Markham, both the first and second part carry grooves. However, the grooves on the first part are not in registry with the grooves in the second part, since the first and second part form a gear. In a gear, the grooves on one part must register with the projections of the second part.

12. The following is an examiner's statement of reasons for allowance: Although both Markham and Sackier et al. teach medical devices having projections on a contact area between two parts, the prior art fails to teach or suggest a plurality of projections located randomly on the contact area.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

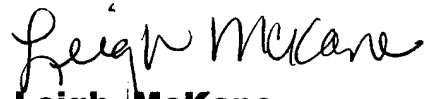
### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (5:30 am-3:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
11 July 2005